

JUL 11 2007

K071182

#### 1.4 510(k) Summary of Safety and Effectiveness

Submitted by: Ms. Phuong Nguyen Son  
Regulatory Affairs Specialist

Address: Nobel Biocare USA LLC  
22715 Savi Ranch Parkway  
Yorba Linda, CA 92887

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Date of Submission: April 26, 2007

Classification Name: Porcelain Tooth (21 CFR 872.3920)

Trade or Proprietary  
or Model Name: Procera Bridge Zirconia

Legally Marketed Device(s): Procera Bridge Zirconia (K053125)

##### Device Description:

Nobel Biocare's Procera Bridge Zirconia is a prefabricated device intended for use as the core structure of an artificial prosthesis for placement in the oral cavity in order to restore chewing function. The Procera Bridge Zirconia is precision milled from one solid piece of densely sintered Zirconia, and can be cemented or bonded to either natural or artificial tooth abutments.

##### Indications for Use:

Nobel Biocare's Procera Bridge Zirconia is indicated for use as the core structure of an artificial prosthesis for partially edentulous patients in the need of prosthetic oral reconstruction in order to restore chewing function. The Procera Bridge Zirconia may be cemented or bonded to either natural or artificial tooth abutments.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

JUL 11 2007

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Nobel Biocare AB  
C/O Phuong Nguyen Son  
Regulatory Affairs Specialist  
Nobel Biocare USA LLC  
22715 Savi Ranch Parkway  
Yorba Linda, California 92887

Re: K071182

Trade/Device Name: Procera Bridge Zirconia  
Regulation Number: 21 CFR 872.3920  
Regulation Name: Porcelain Tooth  
Regulatory Class: II  
Product Code: ELL  
Dated: April 26, 2007  
Received: April 30, 2007

Dear Ms. Son:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Chiu Lin, Ph.D.

Director

Division of Anesthesiology, General Hospital,

Infection Control and Dental Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

### 1.3

### Indications for Use

510(k) Number (if known): K071182

Device Name: Procera Bridge Zirconia

Indications For Use:

Nobel Biocare's Procera Bridge Zirconia is indicated for use as the core structure of an artificial prosthesis for partially edentulous patients in the need of prosthetic oral reconstruction in order to restore chewing function. The Procera Bridge Zirconia may cemented or bonded to either natural or artificial tooth abutments.

Prescription Use X  
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Karin Mulvey for MSR  
(Division Sign-Off)

Division of Anesthesiology, General Hospital  
Infection Control, Dental Devices

510(k) Number: K071182

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